K053530

JAN 3 2006

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR, Part 807, Subpart E, Section 807.92.

1. Submitter's Information: 21 CFR 807.92(a)(1)

Medison Co. Ltd.
997-10, Daechi-dong, Gangnam-gu,
Seoul 135-280, Korea

Contact Person:
Mr. Kyung-Am, Shim
Regulatory Affairs Manager

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Email: kashim@medison.com

Data Prepared:
November 10, 2005

2. Name of the device:

Common/Usual Name:

Diagnostic Ultrasound System and Accessories

Proprietary Name:

SONOACE X4 Diagnostic Ultrasound System

Classification Names:	FR Number	Product Code
Ultrasonic Pulsed Doppler Imaging System	892.1550	90-IYN
Ultrasound Pulsed Echo Imaging System	892.1560	90-IYO
Diagnostic Ultrasound Transducer	892.1570	90-ITX

3. Identification of the predicate or legally marketed device:

K012887, 09/12/2001, SA6000II Ultrasound system
K043455, 12/21/2004, SA8000SE Ultrasound system

4. Device Description:

The SONOACE X4 is a general purpose, mobile, software controlled, diagnostic ultrasound system with on-screen display for themal and mechanical indices related to potential bioeffect mechanisms.. Its function is to acquire ultrasound data and to display the data as 2D (B) mode, M mode, Power Doppler imaging, Harmonic imaging, or 3D imaging on the CRT display.

The SONOACE X4 has been designed to meet the following product safety standards:

- UL 60601-1, Safety requirements for Medical Equipment
- CSA C22.2 No. 601.1, Safety requirements for Medical Equipment
- IEC60601-2-37, Diagnostic Ultrasound Safety Standards
- EN/IEC60601-1, Safety requirements for Medical Equipment
- EN/IEC60601-1-2, EMC requirements for Medical Equipment y
- NEMA UD 2-2004 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
- NEMA UD 3-2004 Standard for Real Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
- IEC 61157, Declaration of the acoustic output
- ISO10993, Biocompatibility

5. Intended Uses:

The SONOACE X4 system is intended for the following applications:
General, OB, Gynecology, Abdomen, Fetal Heart, Renal, Neonatal, Pediatric, Vascular, Cardiac, Urology, Breast, Small Parts, Vascular, Musculoskeletal applications.

The system also provides for the measurement of anatomical structures and for analysis packages that provide information that is used for clinical diagnosis purposes.

6. Technological Characteristics:

The SONOACE X4 is substantially equivalent to the SA6000II Diagnostic Ultrasound System, cleared via K012887, and the SA8000 SE Diagnostic Ultrasound System, cleared via K043455. All systems transmit ultrasonic energy into patients, then perform post processing of received echoes to generate on-screen display of anatomic structures and fluid flow within the body. All system allow for specialized measurements of structures and flow, and calculations.

END of 510(K) Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 3 2006

Medison C., Ltd.
c/o Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K053530
Trade Name: SONOACE X4 Diagnostic Ultrasound System
Regulation Number: 21 CFR §892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Product Code: IYN
Regulation Number: 21 CFR §892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Product Code: IYO
Regulation Number: 21 CFR §892.1570
Regulation Name: Diagnostic ultrasonic transducer
Product Code: ITX
Regulatory Class: II
Dated: December 15, 2005
Received: December 19, 2005

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the SONOACE X4 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

HL5-9ED	L5-9EC	L5-9EE
C2-4ES	C2-5ET	C3-7ED
C4-9ED	EC4-9ED	EC4-9ES

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Mr. Rodrigo Perez at (301) 594-1212.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Diagnostic Ultrasound Indications for Use Form

510(k) Number:
Device Name: SONOACE X4 Diagnostic Ultrasound System
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler*	Power (Amp) Doppler	Color Velocity Imaging	Combined (Spec.)	Other (Specify)
Ophthalmic										
Fetal		N	N	N					Notes 1	Notes 3, 5, 6
Abdominal		N	N	N					Notes 1	Notes 3, 5, 6
Intra-Operative *(See Note 4)*		N	N	N					Notes 1	Notes 3, 5, 6
Intra-Operative Neurological										
Pediatric		N	N	N					Notes 1	Notes 3, 5, 6
Small Organ *(See Note 2)*		N	N	N					Notes 1	Notes 3, 5, 6
Neonatal Cephalic		N	N	N					Notes 1	Note 5
Adult Cephalic		N	N	N					Notes 1	Note 5
Cardiac		N	N	N					Notes 1	Note 5
Transesophageal										
Trans-Rectal		N	N	N					Notes 1	Notes 3, 5
Trans-Vaginal		N	N	N					Notes 1	Notes 3, 5
Trans-Urethral										
Intra-Vascular										
Peripheral -Vascular		N	N	N					Notes 1	Note 5
Laparoscopic										
Muscular-Skeletal Conventional		N	N	N					Notes 1	Notes 3, 5, 6
Muscular-Skeletal Superficial		N	N	N					Notes 1	Notes 3, 5, 6
Others(Specify)										

N = new indication; P = previously cleared by FDA; E = added under Appendix E
Additional Comments:
Note 1: B/M, B/PW Doppler
Note 2: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 3: Includes imaging for guidance of biopsy
Note 4: Abdominal organs and peripheral vessel
Note 5: 3D Imaging
Note 6: Harmonic Imaging

Concurrence of CDRH, Office of Device Evaluation(ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K053530

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

510(k) Number:
Device Name: HL5-9ED for use with SONOACE X4
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler*	Power (Amp) Doppler	Color Velocity Imaging	Combined (Spec.)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-Operative *(See Note 4)*										
Intra-Operative Neurological										
Pediatric		P	P	P					Note 1	Notes 3, 5
Small Organ *(See Note 2)*		P	P	P					Note 1	Notes 3, 5
Neonatal Cephalic		P	P	P					Note 1	Notes 3, 5
Adult Cephalic										
Cardiac										
Transesophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Vascular										
Peripheral -Vascular		P	P	P					Note 1	Note 5
Laparoscopic										
Muscular-Skeletal Conventional		P	P	P					Note 1	Notes 3, 5
Muscular-Skeletal Superficial		P	P	P					Note 1	Notes 3, 5
Others(Specify)										

N = new indication; P = previously cleared in K043455; E = added under Appendix E
Additional Comments:
Note 1: B/M, B/PW Doppler
Note 2: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 3: Includes imaging for guidance of biopsy
Note 4: Abdominal organs and peripheral vessel
Note 5: 3D Imaging
Note 6: Harmonic Imaging

Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription Use (Per 21 CFR 801.109)

David A. Lyerly
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K053530

Diagnostic Ultrasound Indications for Use Form

510(k) Number:
Device Name: L5-9EC for use with SONOACE X4
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler*	Power (Amp) Doppler	Color Velocity Imaging	Combined (Spec.)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal		P	P	N					Note 1	Notes 3, 5
Intra-Operative *(See Note 4)*		P	P	N					Note 1	Notes 5
Intra-Operative Neurological										
Pediatric		P	P	N					Note 1	Notes 3, 5
Small Organ *(See Note 2)*		P	P	N					Note 1	Notes 3, 5
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Vascular										
Peripheral -Vascular		P	P	N					Note 1	Note 5
Laparoscopic										
Muscular-Skeletal Conventional		P	P	N					Note 1	Notes 3, 5
Muscular-Skeletal Superficial		P	P	N					Note 1	Notes 3, 5
Others(Specify)										

N = new indication; P = previously cleared in K012887 ; E = added under Appendix E
Additional Comments:
Note 1: B/M, B/PW Doppler
Note 2: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 3: Includes imaging for guidance of biopsy
Note 4: Abdominal organs and peripheral vessel
Note 5: 3D Imaging
Note 6: Harmonic Imaging

Concurrence of CDRH, Office of Device Evaluation(ODE)

David B. Lilyman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K053530

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

510(k) Number:
Device Name: L5-9EE for use with SONOACE X4
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler*	Power (Amp) Doppler	Color Velocity Imaging	Combined (Spec.)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-Operative *(See Note 4)*										
Intra-Operative Neurological										
Pediatric		P	P	P					Note 1	Notes 3, 5
Small Organ *(See Note 2)*		P	P	P					Note 1	Notes 3, 5
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Vascular										
Peripheral -Vascular		P	P	P					Note 1	Note 5
Laparoscopic										
Muscular-Skeletal Conventional		P	P	P					Note 1	Notes 3, 5
Muscular-Skeletal Superficial		P	P	P					Note 1	Notes 3, 5
Others(Specify)										

N = new indication; P = previously cleared in K043455 ; E = added under Appendix E
Additional Comments:
Note 1: B/M, B/PW Doppler
Note 2: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 3: Includes imaging for guidance of biopsy
Note 4: Abdominal organs and peripheral vessel
Note 5: 3D Imaging
Note 6: Harmonic Imaging

Concurrence of CDRH, Office of Device Evaluation(ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K053530

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

510(k) Number:
Device Name: C2-4ES for use with SONOACE X4
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler*	Power (Amp) Doppler	Color Velocity Imaging	Combined (Spec.)	Other (Specify)
Ophthalmic										
Fetal		P	P	N					Note 1	Note 5
Abdominal		P	P	N					Note 1	Note 5
Intra-Operative *(See Note 4)*		P	P	N					Note 1	Note 5
Intra-Operative Neurological										
Pediatric		P	P	N					Note 1	Note 5
Small Organ *(See Note 2)*		P	P	N					Note 1	Note 5
Neonatal Cephalic		P	P	N					Note 1	Note 5
Adult Cephalic		P	P	N					Note 1	Note 5
Cardiac		P	P	N					Note 1	Note 5
Transesophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Vascular										
Peripheral -Vascular		P	P	N					Note 1	Note 5
Laparoscopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others(Specify)										

N = new indication; P = previously cleared in K012887 ; E = added under Appendix E
Additional Comments:
Note 1: B/M, B/PW Doppler
Note 2: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 3: Includes imaging for guidance of biopsy
Note 4: Abdominal organs and peripheral vessel
Note 5: 3D Imaging
Note 6: Harmonic Imaging

Concurrence of CDRH, Office of Device Evaluation(ODE)

David A. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K053530

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

510(k) Number:
Device Name: C2-5ET for use with SONOACE X4
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler*	Power (Amp) Doppler	Color Velocity Imaging	Combined (Spec.)	Other (Specify)
Ophthalmic										
Fetal		P	P	P					Note 1	Note 5
Abdominal		P	P	P					Note 1	Note 5
Intra-Operative *(See Note 4)*										
Intra-Operative Neurological										
Pediatric		N	N	N					Note 1	Note 5
Small Organ *(See Note 2)*										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Vascular										
Peripheral -Vascular										
Laparoscopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others(Specify)										

N = new indication; P = previously cleared in K043455 ; E = added under Appendix E
Additional Comments:
Note 1: B/M, B/PW Doppler
Note 2: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 3: Includes imaging for guidance of biopsy
Note 4: Abdominal organs and peripheral vessel
Note 5: 3D Imaging
Note 6: Harmonic Imaging

Concurrence of CDRH, Office of Device Evaluation(ODE)

David A. Lagomarsino

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K053530

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

510(k) Number:
Device Name: C3-7ED for use with SONOACE X4
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler*	Power (Amp) Doppler	Color Velocity Imaging	Combined (Spec.)	Other (Specify)
Ophthalmic										
Fetal		P	P	P					Note 1	Notes 3, 5, 6
Abdominal		P	P	P					Note 1	Notes 3, 5, 6
Intra-Operative *(See Note 4)*		P	P	N					Note 1	Notes 5, 6
Intra-Operative Neurological										
Pediatric		P	P	P					Note 1	Notes 3, 5, 6
Small Organ *(See Note 2)*		P	P	N					Note 1	Notes 3, 5, 6
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Vascular										
Peripheral -Vascular										
Laparoscopic										
Muscular-Skeletal Conventional		P	P	N					Note 1	Notes 3, 5, 6
Muscular-Skeletal Superficial		P	P	N					Note 1	Notes 3, 5, 6
Others(Specify)										

N = new indication; P = previously cleared in K012887 & K043455 ; E = added under Appendix E
Additional Comments:
Note 1: B/M, B/PW Doppler
Note 2: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 3: Includes imaging for guidance of biopsy
Note 4: Abdominal organs and peripheral vessel
Note 5: 3D Imaging
Note 6: Harmonic Imaging

Concurrence of CDRH, Office of Device Evaluation(ODE)

David R. Lyon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K053530

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

510(k) Number:
Device Name: C4-9ED for use with SONOACE X4
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler*	Power (Amp) Doppler	Color Velocity Imaging	Combined (Spec.)	Other (Specify)
Ophthalmic										
Fetal		P	P	P					Note 1	Notes 3, 5
Abdominal										
Intra-Operative *(See Note 4)*										
Intra-Operative Neurological										
Pediatric										
Small Organ *(See Note 2)*		P	P	P					Note 1	Notes 3, 5
Neonatal Cephalic		P	P	P					Note 1	Notes 5
Adult Cephalic										
Cardiac										
Transesophageal										
Trans-Rectal		P	P	P					Note 1	Notes 3, 5
Trans-Vaginal		P	P	P					Note 1	Notes 3, 5
Trans-Urethral										
Intra-Vascular										
Peripheral -Vascular		P	P	P					Note 1	Notes 3, 5
Laparoscopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others(Specify)										

N = new indication; P = previously cleared in K043455; E = added under Appendix E
Additional Comments:
Note 1: B/M, B/PW Doppler
Note 2: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 3: Includes imaging for guidance of biopsy
Note 4: Abdominal organs and peripheral vessel
Note 5: 3D Imaging
Note 6: Harmonic Imaging

Concurrence of CDRH, Office of Device Evaluation(ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K053530

Diagnostic Ultrasound Indications for Use Form

510(k) Number:
Device Name: EC4-9ED for use with SONOACE X4
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler*	Power (Amp) Doppler	Color Velocity Imaging	Combined (Spec.)	Other (Specify)
Ophthalmic										
Fetal		P	P	P					Note 1	Notes 3, 5
Abdominal										
Intra-Operative *(See Note 4)*										
Intra-Operative Neurological										
Pediatric										
Small Organ *(See Note 2)*										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Trans-Rectal		P	P	P					Note 1	Notes 3, 5
Trans-Vaginal		P	P	P					Note 1	Notes 3, 5
Trans-Urethral										
Intra-Vascular										
Peripheral -Vascular										
Laparoscopic										
Muscular-Skeletal Conventional										
Muscular-Skeletal Superficial										
Others(Specify)										

N = new indication; P = previously cleared in K043455; E = added under Appendix E
Additional Comments:
Note 1: B/M, B/PW Doppler
Note 2: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 3: Includes imaging for guidance of biopsy
Note 4: Abdominal organs and peripheral vessel
Note 5: 3D Imaging
Note 6: Harmonic Imaging

Concurrence of CDRH, Office of Device Evaluation(ODE)

David R. Hoffmann

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K053530

Prescription Use (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form

510(k) Number:
Device Name: EC4-9ES for use with SONOACE X4
Intended Use: Ultrasound imaging or fluid flow analysis of the human body as follows:

Mode of Operation

Clinical Application	A	B	M	PWD	CWD	Color Doppler*	Power (Amp) Doppler	Color Velocity Imaging	Combined (Spec.)	Other (Specify)
Ophthalmic										
Fetal		P	P	P					Note 1	Notes 3, 5
Abdominal		P	P	P					Note 1	Notes 3, 5
Intra-Operative *(See Note 4)*		P	P	P					Note 1	Notes 3, 5
Intra-Operative Neurological										
Pediatric		P	P	P					Note 1	Notes 3, 5
Small Organ *(See Note 2)*		P	P	P					Note 1	Notes 3, 5
Neonatal Cephalic		P	P	P					Note 1	Notes 5
Adult Cephalic										
Cardiac										
Transesophageal										
Trans-Rectal		P	P	P					Note 1	Notes 3, 5
Trans-Vaginal		P	P	P					Note 1	Notes 3, 5
Trans-Urethral										
Intra-Vascular										
Peripheral -Vascular		P	P	P					Note 1	Notes 3, 5
Laparoscopic										
Muscular-Skeletal Conventional		P	P	P					Note 1	Notes 3, 5
Muscular-Skeletal Superficial		P	P	P					Note 1	Notes 3, 5
Others(Specify)										

N = new indication; P = previously cleared in K012887; E = added under Appendix E
Additional Comments:
Note 1: B/M, B/PW Doppler
Note 2: For example: thyroid, parathyroid, breast, scrotum and penis in adult, pediatric and neonatal patients
Note 3: Includes imaging for guidance of biopsy
Note 4: Abdominal organs and peripheral vessel
Note 5: 3D Imaging
Note 6: Harmonic Imaging

Concurrence of CDRH, Office of Device Evaluation(ODE)

David R. Lehman

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K033530

Prescription Use (Per 21 CFR 801.109)